

### **Subpart C—Human Drugs; Redelegations of Authority**

#### **§ 5.100 Issuance of notices implementing the provisions of the Drug Amendments of 1962.**

The Director, the Deputy Director, and the Directors, Office of Review Management and Office of Pharmaceutical Science, Center for Drug Evaluation and Research; and the Director, the Deputy Directors for Regulations and Policy and for Science, and the Director and Deputy Directors, Office of Device Evaluation, Center for Devices and Radiological Health, are authorized to issue notices and amendments thereto implementing section 107(c)(3) of the Drug Amendments of 1962 (Pub. L. 87–781) by announcing new or revised efficacy findings on human drugs that are or were subject to the provisions of section 506 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355). These officials may not further redelegate this authority.

#### **§ 5.101 Termination of exemptions for new drugs for investigational use in human beings.**

(a) The following officials, for drugs under their jurisdiction, are authorized to perform all the functions of the Commissioner of Food and Drugs on the termination of exemptions for new drugs (including those that are biological products which are subject to the licensing provisions of the Public Health Service Act) for investigational use in human beings under § 312.44 of this chapter and in animals under § 312.160 of this chapter:

(1) The Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER).

(2) The Director, the Deputy Director, and the Directors, Office of Review Management and Pharmaceutical Science, Center for Drug Evaluation and Research (CDER).

(3) The Director and Deputy Directors for Science and for Regulations and Policy, Center for Devices and Radiological Health (CDRH).

(b) The following officials, for drugs under their jurisdiction, are authorized to terminate exemptions for new drugs for investigational use when sponsors fail to submit an annual progress re-

port under § 312.44(b)(1)(viii) of this chapter:

(1) The Directors and Deputy Directors of the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.

(2) The Directors and Deputy Directors of the divisions in the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.

(3) The Directors and Deputy Directors, Office of Blood Research and Review (OBRR), OVR, and Office of Therapeutics Research and Review (OTRR), CBER.

(4) The Directors and Deputy Directors of the Division of Blood Applications, OBRR, the Division of Vaccines and Related Products Applications, OVR, and the Division of Application Review and Policy, OTRR, CBER.

(5) The Director and Deputy Directors, Office of Device Evaluation (ODE), CDRH.

(c) The following officials, for drugs under their jurisdiction, are authorized to make the findings set forth in § 312.44(b) of this chapter and to notify sponsors and invite correction before termination action on such exemptions:

(1) The Directors and Deputy Directors of the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.

(2) The Directors and Deputy Directors of the divisions in the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.

(3) The Directors and Deputy Directors, Office of Blood Research and Review (OBRR), Office of Vaccines Research and Review (OVR), and Office of Therapeutics Research and Review (OTRR), CBER.

(4) The Directors and Deputy Directors of the Division of Blood Applications, OBRR, the Division of Vaccines and Related Products Applications, OVR, and the Division of Application Review and Policy, OTRR, CBER.

(5) The Director and Deputy Directors, ODE, CDRH.

(d) These officials may not further redelegate these authorities.